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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,066	08/23/2001	Hisakazu Katsuki	KATSUKI=1	8579

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EXAMINER

WARE, TODD

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/914,066

Applicant(s)

KATSUKI, HISAKAZU

Examiner

Todd D Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-14,16 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-14,16 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Receipt of information disclosure statements filed 10-25-02 and 1-10-03 and request for extension of time (granted) and amendment filed 4-1-03 is acknowledged. Claims 3-5, 15 and 17 have been canceled and claims 1-2 have been amended and new claim 18 has been added. Claims 1-2, 6-14, 16 and 18 are pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. **Claims 1-2, 6-14, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borkan et al (4,935,243; hereafter '243) in view of Cynshi et al (WO 97/17066; hereafter '066 –US 6,103,753 is relied upon as a translation of '066).**

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4. '243 teaches hermetically sealed soft gelatin capsules (seamed soft gelatin capsules) filled with a vegetable oil such as soybean oil that deliver a water insoluble active agent (4-(2-nitrophenyl)-2,6-dimethyl-3,5-dicarbomethoxy-1,4-dihydropyridine AKA nifedipine). The shell of '243 also contains sorbitol and glycerin as plasticizers.
5. '066 teaches capsules for the instant active agents to treat arteriosclerosis.
6. Accordingly, absent a demonstration of criticality, it would have been obvious to one skilled in the art at the time of the invention to combine the above references with the motivation of providing an oral means for administering the hydrophobic active agent of '066 in a dosage form that provides a carrier for the active agent. The limitations requiring concentrated glycerin are not considered critical since the glycerin is ultimately diluted with the gelatin/sorbitol/glycerin formulation. Upon addition of the concentrated glycerin, the concentrated glycerin becomes diluted. Therefore, concentrated glycerin does not appear to be critical in the absence of a demonstration of criticality. Newly added claim 18 is also considered obvious to one skilled in the art at the time of the invention. While '243 teaches that further ingredients may be included in the fill material, it does not teach that they are required (i.e. they are optional components). Accordingly, the requirement that the fill solution is "substantially free of any other component" does not impart patentability over the instant rejection.

Response to Arguments

7. Applicant's arguments filed 4-1-03 have been fully considered but they are not persuasive. Applicant argues that the instant rejection should be withdrawn on the basis that neither '243 or '066 teaches the improved stability of the compound of instant

claim 2 (hereafter BO-653), citing Examples 1-2 and Figure 1. However, these examples do not provide any statistical evaluation of the results and the Examiner is unable to determine whether the asserted differences seen are statistically significant or whether they are due to inherent variation/variability within the sample and the test. It is further noted that the instant examples are directed toward BO-653 and no evidence that the results of these examples apply equally to the capsules containing the broadly claimed compounds of instant claims 1 and 18. This is also the case for Applicant's arguments regarding increased absorbability of the instant composition. Accordingly, the Examiner is unable to determine that the results are non-obvious and Applicant's arguments are not persuasive.

8. Applicant further argues that '243 does not focus on soybean oil when listing the fill materials of column 5, lines 43-45 (and 53-55), stating, "the choices are extremely great, and picking any particular fill material is basically akin to figuring out the combination of a safe merely by looking at the dial." Determination of obviousness is on the basis that the number of species is small (5 vegetable oils as well as a mixture of polyalkylene glycol and lower alcohols). It is noted that the mere fact that a prior art genus contains a small number of members does not create a per se rule of obviousness. Some motivation to select the claimed species or subgenus must be taught by the prior art. *In re Baird*, 16 F.3d at 383, 29 USPQ2d 1550 (CAFC 1994). In this determination, it is first noted that '243 teaches the same seamed soft capsules and therefore teaches the same dosage form and there is no teaching away from one species for another. Accordingly, there is expectation that the claimed subject matter

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will function in an equivalent manner to the genus. Furthermore, '243 teaches that the members have similar properties and uses (e.g. solvent base fill material for soft gelatin capsules). In *In re Dillon*, 919 F.2d at 697, 16 USPQ2d at 1897, the CAFC established that if the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species. Furthermore, while if the technology is unpredictable, it is less likely that structurally similar species will render a claimed species obvious because it may not be reasonable to infer that they would share similar properties as in *In re May*, 574 F.2d 1082, 1094, 197 USPQ 601, 611 (CCPA 1978). However, the instant technology is predictable. Furthermore, in view that insufficient evidence to establish unobviousness has been provided, the criticality of soybean oil has not been established. Accordingly, the evidence as a whole supports a *prima facie* case that the claimed invention would have been obvious to one of ordinary skill in the relevant art at the time the invention was made.

9. **Claims 1-2, 6-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borkan et al (4,935,243; hereafter '243) in combination with Cynshi et al (WO 97/17066; hereafter '066 –US 6,103,753 is relied upon as a translation of '066) and further in combination with Demichele et al (6,013,665; hereafter '665.**

10. '243 and '066 are relied upon for all that they teach as stated previously.

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11. '665 further elaborates on teachings *supra*, teaching that the absorption of lipophilic compounds is enhanced by concurrent administration of the lipophilic compound and an oil such as soybean oil.

12. Accordingly, absent a demonstration of criticality, it would have been obvious to one skilled in the art at the time of the invention to combine the above references with the motivation of enhancing the oral delivery of the instant lipophilic active agent. Limitations requiring concentrated glycerin are not considered critical since the glycerin is ultimately diluted with the gelatin/sorbitol/glycerin formulation. Upon addition of the concentrated glycerin, the concentrated glycerin becomes diluted. Therefore, concentrated glycerin does not appear to be critical in the absence of a demonstration of criticality. Newly added claim 18 is also considered obvious to one skilled in the art at the time of the invention. While '243 teaches that further ingredients may be included in the fill material, it does not teach that they are required (i.e. they are optional components). Accordingly, the requirement that the fill solution is "substantially free of any other component" does not impart patentability over the instant rejection.

Response to Arguments

13. Applicant's arguments filed 4-1-03 have been fully considered but they are not persuasive. Applicant argues that the instant rejection should be withdrawn on the basis of argument responded to in paragraphs 11 and 12, *supra* (and are again relied upon here), and that '665 teaches a combination of lipophilic compound with a structured glyceride component containing a long chain triglyceride (soybean oil) and medium chain triglyceride in a certain proportion. Applicant continues that the

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combination of references would not suggest that soybean oil by itself would be able to enhance the absorption of lipophilic compound. In response, it is pointed out that the claims rejected recite comprising language and therefore do not exclude inclusion of other elements in the fill material. Accordingly, Applicant's arguments are not persuasive.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw
June 3, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600